DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Serge R. Martinod
Agent for Naturaleaf, Inc.
37 Skyline Drive
Groton, Connecticut 06340

AUG 12 2005

Dear Mr. Martinod:

This is to inform you that the notification, dated May 24, 2005, you submitted on behalf of your client, Naturaleaf, Inc., pursuant to 21 U.S.C. 350b(a) (2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 1, 2005. Your notification concerns the substance called "*Canarium indicum* nut oil" that you intend to market as a new dietary ingredient.

According to the notification, Naturaleaf, Inc. intends to market the new dietary ingredient "*Canarium indicum* nut oil" in the form of soft gel or gel capsules. The notification stated that the recommended daily intake will be 1 drop or 1 capsule 3 times a day with each meal. This will result in an intake of 200 mg/day. The notification also stated that the dietary ingredient will contain 100% nut oil.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "*Canarium indicum* nut oil" will reasonably be expected to be safe.

Your notification failed to adequately identify your new dietary ingredient, "*Canarium indicum* nut oil." While your notification included a flow diagram of a manufacturing process, this information did not adequately establish the identity of "*Canarium indicum* nut oil." For example, you supplied a nutrient profile (TLC & GC) of free fatty acids found in a typical nut (approximately 48% by weight of saturated fat, 38% monosaturated fat, 14% PUFA, 13% protein, 7%, carbohydrates with small amounts of minerals and vitamins), but provided no specific information regarding the methods of analysis, composition, or purity of "*Canarium indicum* nut oil" that is the subject of your notification. In addition, the amount of "*Canarium indicum* nut oil" in an unspecified volume of one drop that constitutes a serving size of your product is unclear.

Your notification stated there is a long history of use of *Canarium indicum* nuts and nut oil mixtures as food in tropical Asia, South Western Pacific, Melanesia, and New Zealand and you cited scientific publications that discuss the safety of diets that contain nut mixtures, including pine nut oil, but not the *Canarium indicum* nut oil that is the subject of your notification.

In addition, your notification included safety data on nut oil mixtures but not on your proposed new dietary ingredient, "*Canarium indicum* nut oil," or your dietary supplement containing your new dietary ingredient, "*Canarium indicum* nut oil." Therefore, it is not clear how the substances discussed in the referenced scientific studies are qualitatively or quantitatively similar to your new dietary ingredient, "*Canarium indicum* nut oil," or how these studies are relevant in evaluating the safe use of your dietary supplement product containing your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "*Canarium indicum* nut oil," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of June 1, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition